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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,673	01/10/2001	James M. Wilson	GNVPN.019B1USA	8771

270 7590 05/10/2004

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,673

Applicant(s)

WILSON ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-10-04 has been entered.

2. Regarding applicants communication of 4-22-04, it is noted that as indicated by the applicants in this communication, the claim limitation "at least as free of contamination with a help virus as obtained by subjecting the rAAV to four rounds of cesium chloride gradient centrifugation" was discussed in the telephonic interview on 3-15-04.

3. Applicants' response filed 2-10-04 has been received.

4. Claims 7-10 and 12-26 are pending and under consideration in the instant application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7-10 and 12-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 7-30-02 and 11-15-03.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-10 and 12-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in the previous office action of 7-30-02 and 11-15-03.

Response to Arguments

Applicants have argued both 112 first and second paragraph rejections together. Accordingly, the applicant's arguments' arguments are responded together.

Applicants have argued that on page 35, lines 1-5 the specification teaches that rAAV purified according to the invention contains no detectable amounts of contaminating adenovirus. However, as noted in the previous office action, the recited phrase encompasses "equal to" or "more" pure recombinant AAV composition compared to the preparation of recombinant AAV obtained after four rounds of cesium chloride centrifugation. However, the specification does not provide written support either for the phrase it self or for equal to or more pure AAV preparation compared to that obtained by four rounds of cesium chloride centrifugation. Regarding applicants' arguments that an artisan could detect the amount of contaminating adenovirus in a rAAV preparation, "no detectable amount" can not provide support for the phrase recited because the "no detectable amount" is a relative term and could defer based on the definition of what is considered detectable. Even if one agreed that the term "no detectable amount" is a definite term, the term "no detectable amount" can only describe the "equal to" part of the recited limitation. If "the equal to" indicates no detectable amount, then what is encompassed by "more" pure than that prepared by four rounds of purification. Therefore, the metes and bounds of the claimed invention are not clear. Applicants arguments that the inventors were first to have found that

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contamination of rAAV with adenovirus helper virus was responsible for immune response is not relevant to the issue of written description.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 7-10 and 12-24 and newly presented claims 25-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,866,552 (Wilson JM et al., 2-2-1999) for reasons of record set forth in the previous office action of 11-23-01, 7-30-02 and 11-15-03.

10. Claims 7-10 and 12-24 and newly presented claims 25-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-24 and 26-28 and 30-35 of co-pending Application No. 09/242,977 for reasons of record set forth in the previous office action of 11-23-02 for reasons of record set forth in the previous office action of 11-23-01, 7-30-02 and 11-15-03.

Applicants' response that they will file a terminal disclaimer over 552 patent and the co-pending applications 09/237,064 and 09/242,977 is acknowledged.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 7-10, 18 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Podsakoff et al (US 5,858,351, 1-12-1999, filing date 1-18-1996, ref. # AI in the IDS filed 3-16-01) for reasons of record set forth in the previous office action of 11-23-01, 7-30-02 and 11-15-03.

Response to Arguments

Applicant's arguments filed 11-15-03 have been fully considered but they are not persuasive. It is noted that the arguments presented were reiterations of the previously presented arguments which have been addressed before.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 7-10 and 18-24 and newly presented claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Podsakoff et al (US 5,858,351, 1-12-1999, filing date 1-18-1996, ref. # AI in the IDS filed 3-16-01) in view of Kashyap et al. (Journal of Clinical Investigation 96:1612-1620, ref# CU in the IDS

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filed 3-16-01) for reasons of record set forth in the previous office action of 11-23-01, 7-30-02, 11-15-03.

Response to Arguments

Applicant's arguments filed 11-15-03 have been fully considered but they are not persuasive. It is noted that the arguments presented were reiterations of the previously presented arguments which have been addressed before.

15. Claims 7-10 and 12-17 and newly presented claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Podsakoff et al 1999 in view of Fang et al 1995 (Fang B et al Human Gene Therapy 6:1039-1044, 1995, ref. # CS in the IDS filed 3-126-01) and Kay et al (US 5,980, 886, 11-9-1999) for reasons of record set forth in the previous office action of 11-23-01, 10-30-02 and 11-15-03.

Response to Arguments

Applicant's arguments filed 11-15-03 have been fully considered but they are not persuasive. It is noted that the arguments presented were reiterations of the previously presented arguments which have been addressed before.

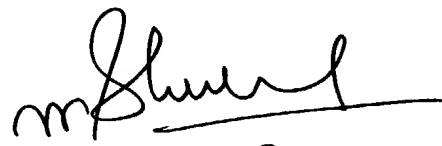
16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (571) 272-0548.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632



**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**